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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,292	04/12/2006	Paul W. Johns	7174USO1	9449

23495 7590 01/16/2009

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EXAMINER	
SMITH, PRESTON	
ART UNIT	PAPER NUMBER
1794	
MAIL DATE	DELIVERY MODE
01/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,292	JOHNS ET AL.	
	Examiner	Art Unit	
	PRESTON SMITH	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *28 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-113* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-113* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/28/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17,18, 36, 37, 77, 78, and 94 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear how the “iron availability agent” would reduce the concentration of soluble unbound iron by at least 50% nor is it clear what properties of the "iron availability agent" of the claims would allow it to achieve this specific reduction (would this specific reduction be attributed to simply the chemical nature of the "availability agent", the amount of the "agent” used, etc.).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1-15, 22-33, 63-75, 81-92, 97-102, 104-108,111-113 rejected under 35 U.S.C. 103(a) as being unpatentable over Bridget Barrett-Reis, US-Patent 6,294,206 in view of iron anemia NPL and as evidenced by solubility NPL and Iron Formulations in Pediatic Practice NPL.

Referring to claim 1, Barrett-Reis teaches a powdered human milk fortifier comprising protein, carbohydrates, and fats (or lipids) (see abstract). Barrett-Reis also teaches that the composition can further comprise iron (column 11, line 44). It is not known if the amount of iron present in Barrett-Reis formula is from about 3 mg to 30 mg per 100 g of human milk fortifier solids (other components of Barrett-Reis's powder) however it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the iron amount (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula(column 10, line 37)) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*). For example, if the

formula is administered to a low weight preterm infant during the 1st 2 months of life and the infant has not had a large amount of blood loss, one of ordinary skill would have realized that since the infant would have sufficient iron stores per body mass, the infant would not have required as much iron as a larger infant and one of ordinary skill would have thus been motivated to provide the preterm infant with iron values within the lower bounds of the claimed range to meet the infant's needs (column 10, lines 35-45) (a larger infant require larger iron content values than the smaller, low weight infant so one of ordinary skill would have been motivated to provide more iron in the formula for a larger infant to meet the larger infant's needs. Also, if the infant is anemic, it would have been obvious to one of ordinary skill to provide iron closer to the upper bound of the claimed range in order to treat the degree of the anemia). Furthermore, it would have been obvious to one of ordinary skill to thus increase or decrease the iron content depending on the needs and/or conditions of the infant in order to provide a human milk fortifier that fits the needs of the specific infant.

Referring to claim 1 again, it is also not known if the type of iron taught by Bridget-Reis is soluble unbound, insoluble, or a combination of the two. Iron anemia NPL teaches that iron preparations that are soluble in water or dilute acids are generally of high bioavailability and forms of iron that are insoluble in water or dilute acids solutions are of low bioavailability (see iron anemia NPL top of page 2). Water-soluble iron tends to react with various components of food to produce oxidative rancidity (iron anemia NPL second paragraph of page 3). It is also known that the greater the solubility (and, the greater the bioavailability) of a metallic iron powder, the greater its chemical

reactivity and the less suitable it is for food fortification (iron anemia NPL second paragraph of page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to select soluble iron or insoluble iron taught by iron anemia NPL for use with the invention of Bridget-Reis since it has been held to be within the general skill of the worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin,* 125 USPQ 416.

Referring to claim 2, it is not known if the amount of iron present in Barrett-Reis formula is from about 10 mg to 110 mg per 100 g of human milk fortifier solids (other components of Barrett-Reis's powder) however it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the iron amount (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula(column 10, line 37)) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*). For example, if the formula is administered to a low weight preterm infant during the 1st 2 months of life and the infant has not had a large amount of blood loss, one of ordinary skill would have realized that since the infant would have sufficient iron stores per body mass, the infant would not have required as much iron as a larger infant and one of ordinary skill would have thus been motivated to provide the preterm infant with iron values within the lower bounds of the claimed range to meet the

infant's needs (column 10, lines 35-45) (a larger infant require larger iron content values than the smaller, low weight infant so one of ordinary skill would have been motivated to provide more iron in the formula for a larger infant to meet the larger infant's needs. Also, if the infant is anemic, it would have been obvious to one of ordinary skill to provide iron closer to the upper bound of the claimed range in order to treat the degree of the anemia). Furthermore, it would have been obvious to one of ordinary skill to thus increase or decrease the iron content depending on the needs and/or conditions of the infant in order to provide a human milk fortifier that fits the needs of the specific infant.

Referring to **claim 2** again, it is also not known if the type of iron taught by Bridget-Reis is soluble unbound, insoluble, or a combination of the two. Iron anemia NPL teaches that iron preparations that are soluble in water or dilute acids are generally of high bioavailability and forms of iron that are insoluble in water or dilute acids solutions are of low bioavailability (see iron anemia NPL iron anemia top of page 2). Water-soluble iron tends to react with various components of food to produce oxidative rancidity (iron anemia NPL second paragraph of page 3). It is also known that the greater the solubility (and, the greater the bioavailability) of a metallic iron powder, the greater its chemical reactivity and the less suitable it is for food fortification (iron anemia NPL second paragraph of page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to select soluble iron or insoluble iron taught by iron anemia NPL for use with the invention of Bridget-Reis since it has been held to be within the general skill of the worker in the art to select a known material on the basis of

its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin,* 125 USPQ 416.

Also it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the selected iron amount in order to produce the claimed ranges (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula (column 10, line 37) and/or based on the other ingredients present in the formula which may react with the type of iron chosen) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*).

Referring to claim 3, it is also not known if the type of iron taught by Bridget-Reis is soluble unbound, insoluble, or a combination of the two. Iron anemia NPL teaches that iron preparations that are soluble in water or dilute acids are generally of high bioavailability and forms of iron that are insoluble in water or dilute acids solutions are of low bioavailability (see iron anemia NPL top of page 2). Water-soluble iron tends to react with various components of food to produce oxidative rancidity (iron anemia NPL second paragraph of page 3). It is also known that the greater the solubility (and, the greater the bioavailability) of a metallic iron powder, the greater its chemical reactivity and the less suitable it is for food fortification (iron anemia NPL second paragraph of page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to select soluble iron or insoluble iron for use with the

invention of Bridget-Reis since it has been held to be within the general skill of the worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin,* 125 USPQ 416.

Also it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the selected iron amount in order to produce the claimed ranges (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula (column 10, line 37) and/or based on the other ingredients present in the formula which may react with the type of iron chosen) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*).

Referring to claim 4, it is not known if the amount of iron present in Barrett-Reis formula is from about 20 mg to 50 mg per 100 g of human milk fortifier solids (other components of Barrett-Reis's powder) however it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the iron amount (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula(column 10, line 37)) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*). For example, if the formula is administered to a low weight preterm infant during the 1st 2 months of life and the infant has not had a large amount

of blood loss, one of ordinary skill would have realized that since the infant would have sufficient iron stores per body mass, the infant would not have required as much iron as a larger infant and one of ordinary skill would have thus been motivated to provide the preterm infant with iron values within the lower bounds of the claimed range to meet the infant's needs (column 10, lines 35-45) (a larger infant require larger iron content values than the smaller, low weight infant so one of ordinary skill would have been motivated to provide more iron in the formula for a larger infant to meet the larger infant's needs. Also, if the infant is anemic, it would have been obvious to one of ordinary skill to provide iron closer to the upper bound of the claimed range in order to treat the degree of the anemia). Furthermore, it would have been obvious to one of ordinary skill to thus increase or decrease the iron content depending on the needs and/or conditions of the infant in order to provide a human milk fortifier that fits the needs of the specific infant.

Referring to claim 5, it is not known if the amount of iron present in Barrett-Reis formula is from about 5 mg to 25 mg per 100 g of human milk fortifier solids (other components of Barrett-Reis's powder) however it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the iron amount (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula(column 10, line 37)) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*). For example, if the formula is administered to a low weight preterm infant during the 1st 2 months of life and the infant has not had a large amount

of blood loss, one of ordinary skill would have realized that since the infant would have sufficient iron stores per body mass, the infant would not have required as much iron as a larger infant and one of ordinary skill would have thus been motivated to provide the preterm infant with iron values within the lower bounds of the claimed range to meet the infant's needs (column 10, lines 35-45) (a larger infant require larger iron content values than the smaller, low weight infant so one of ordinary skill would have been motivated to provide more iron in the formula for a larger infant to meet the larger infant's needs. Also, if the infant is anemic, it would have been obvious to one of ordinary skill to provide iron closer to the upper bound of the claimed range in order to treat the degree of the anemia). Furthermore, it would have been obvious to one of ordinary skill to thus increase or decrease the iron content depending on the needs and/or conditions of the infant in order to provide a human milk fortifier that fits the needs of the specific infant.

Referring to claim 6, iron anemia NPL teaches various forms of iron (see iron anemia NPL, second paragraph, page 3) all usable with the invention of Barret-Reis. Although ferrous sulfate and ferric sulfate can be used to fortify the food also, since ferrous sulfate is known to produce unfavorable side affects such as constipation (see Iron, Ferrous Sulfate-which forms of supplemental iron are best), it is somewhat favorable to not this compounds to the formula. Ferric sulfate absorbs poorly constipation (see Iron, Ferrous Sulfate-which forms of supplemental iron are best) so it's more favorable to use another iron that absorbs better. Because of these known negative attributes of ferrous sulfate and ferric sulfate, it would have been obvious to

one having ordinary skill in the art at the time of the invention to thus fortify the formula without the addition of ferrous sulfate and ferric sulfate.

Referring to claim 7, iron anemia NPL teaches ferrous fumarte (see iron anemia NPL, second paragraph, page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to use ferrous fumarte with the invention of Barrett-Reis because ferrous fumarate is known to be gentle on the digestive system unlike other irons typically used to fortify foods (it does not interfere with the proteolytic or distatic activies of the digestive system) (see Iron formulations in Pediatric Practice NPL, 1st paragraph of ferrous salts section). This feature would make it highly desirable for use in an infant formula.

Referring to claim 8, iron anemia NPL teaches ferrous fumarte (see iron anemia NPL, second paragraph, page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to use ferrous fumarte with the invention of Barrett-Reis because ferrous fumarate is known to be gentle on the digestive system unlike other irons typically used to fortify foods (it does not interfere with the proteolytic or distatic activies of the digestive system) (see Iron formulations in Pediatric Practice NPL, 1st paragraph of ferrous salts section). This feature would make it highly desirable for use in an infant formula.

Referring to claim 9, Barrett-Reis teaches 24-55% protein, 1-30% fats (or lipids), and 15 to 75% carbohydrates of the powder (or fortifier solids, see abstract). Per 100 grams of fortifier solids (powder), the amounts would be from 24-55 g protein, 1-30 g fats (or lipids), and 15 to 75 g.

Referring to claim 10, Barrett-Reis teaches 24-55% protein, 1-30% fats (or lipids), and 15 to 75% carbohydrates of the powder (or fortifier solids, see abstract). Per 100 grams of fortifier solids (powder), the amounts would be from 24-55 g protein, 1-30 g fats (or lipids), and 15 to 75 g. The ranges taught by Barret-Reis substantially overlap and thus are considered to anticipate the claimed ranges.

Additionally, one of ordinary skill in the art at the time of the invention would have considered the invention to have been obvious because the compositional proportions taught by Barret-Reis overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

"The normal desire of scientist or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.", *In re Petersen* 65 USPQ2d 1379 (CAFC 2003).

Referring to claim 11, the composition of Barrett-Reis can be a powder (see abstract).

Referring to claim 12, Barrett-Reis discloses that liquid forms of preterm fortifiers are known (column 2, line 5). Barrett-Reis further discloses that liquid forms of milk fortifiers are advantageous when the mothers milk supply is limited (column 2, lines 61-62). Barrett-Reis does not explicitly disclose a liquid form of the composition however Barrett-Reis does disclose the use of liquid ingredients in the creation of the formula(column 13, line 5). It would have been obvious to one of ordinary skill in the art at the time of the invention to produce a liquid form of the formula of Barrett-Reis by using mostly liquid forms of the compositional ingredients (column 13, line 5) in order to accommodate mothers who can not maintain the level of milk productions levels that is required of their infants.

Referring to claim 13, Barrett-Reis does not teach or disclose the claimed percentages however it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the amounts of the solids compared to the amount of the water in order to produce a known fluidity (viscosity) of the composition for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*. 617, F.2d 272,205 USPQ 215 (CCPA 1980). Furthermore, depending on how thick or thin (viscous or less viscous) one of ordinary skill wanted the formula, it would have been

obvious to one of ordinary skill to adjust the ratio of the solids to the liquids in order to produce this desired viscosity based on what is desired by the infants consuming this formula.

Referring to claim 14, Barrett-Reis does not teach or disclose the claimed percentages however it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the amounts of the solids compared to the amount of the water in order to produce a known fluidity (viscosity) of the composition for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*. 617, F.2d 272,205 USPQ 215 (CCPA 1980). Furthermore, depending on how thick or thin (viscous or less viscous) one of ordinary skill wanted the formula, it would have been obvious to one of ordinary skill to adjust the ratio of the solids to the liquids in order to produce this desired viscosity based on what is desired by the infants consuming this formula.

Referring to claim 15, Barrett-Reis does not teach or disclose the claimed ratios however the composition of Barrett-Reis in view of disclosure could be used in human milk in the claimed ratios.

Referring to claim 22, Barrett-Reis teaches a powdered human milk fortifier comprising protein, carbohydrates, and fats (or lipids) (see abstract). Additionally,

Barrett-Reis teaches that the composition can further comprise iron (column 11, line 44) however Barrett-Reis fails to teach the iron containing material, ferrours fumarte. Iron anemia NPL teaches ferrous fumarte (see iron anemia NPL, second paragraph, page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to use ferrous fumarte with the invention of Barrett-Reis because ferrous fumarate is known to be gentle on the digestive system unlike other irons typically used to fortify foods (it does not interfere with the proteolytic or distatic activies of the digestive system) (see Iron formulations in Pediatric Practice NPL, 1st paragraph of ferrous salts section). This feature would make it highly desirable for use in an infant formula.

Referring to claim 23, it is not known if the amount of iron present in Barrett-Reis formula is from about 10 mg to 110 mg per 100 g of human milk fortifier solids (other components of Barrett-Reis's powder) however it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the iron amount (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula(column 10, line 37)) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*). For example, if the formula is administered to a low weight preterm infant during the 1st 2 months of life and the infant has not had a large amount of blood loss, one of ordinary skill would have realized that since the infant would have sufficient iron stores per body mass, the infant would not have required as

much iron as a larger infant and one of ordinary skill would have thus been motivated to provide the preterm infant with iron values within the lower bounds of the claimed range to meet the infant's needs (column 10, lines 35-45) (a larger infant require larger iron content values than the smaller, low weight infant so one of ordinary skill would have been motivated to provide more iron in the formula for a larger infant to meet the larger infant's needs. Also, if the infant is anemic, it would have been obvious to one of ordinary skill to provide iron closer to the upper bound of the claimed range in order to treat the degree of the anemia). Furthermore, it would have been obvious to one of ordinary skill to thus increase or decrease the iron content depending on the needs and/or conditions of the infant in order to provide a human milk fortifier that fits the needs of the specific infant.

Referring to **claim 23** again, it is also not known if the type of iron taught by Bridget-Reis is soluble unbound, insoluble, or a combination of the two. Iron anemia NPL teaches that iron preparations that are soluble in water or dilute acids are generally of high bioavailability and forms of iron that are insoluble in water or dilute acids solutions are of low bioavailability (see iron anemia NPL iron anemia top of page 2). Water-soluble iron tends to react with various components of food to produce oxidative rancidity (iron anemia NPL second paragraph of page 3). It is also known that the greater the solubility (and, the greater the bioavailability) of a metallic iron powder, the greater its chemical reactivity and the less suitable it is for food fortification (iron anemia NPL second paragraph of page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to select soluble iron or insoluble iron taught by

iron anemia NPL for use with the invention of Bridget-Reis since it has been held to be within the general skill of the worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin,* 125 USPQ 416.

Also it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the selected iron amount in order to produce the claimed ranges (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula (column 10, line 37) and/or based on the other ingredients present in the formula which may react with the type of iron chosen) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*).

Referring to claim 24, it is also not known if the type of iron taught by Bridget-Reis is soluble unbound, insoluble, or a combination of the two. Iron anemia NPL teaches that iron preparations that are soluble in water or dilute acids are generally of high bioavailability and forms of iron that are insoluble in water or dilute acids solutions are of low bioavailability (see iron anemia NPL top of page 2). Water-soluble iron tends to react with various components of food to produce oxidative rancidity (iron anemia NPL second paragraph of page 3). It is also known that the greater the solubility (and, the greater the bioavailability) of a metallic iron powder, the greater its chemical

reactivity and the less suitable it is for food fortification (iron anemia NPL second paragraph of page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to select soluble iron or insoluble iron for use with the invention of Bridget-Reis since it has been held to be within the general skill of the worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin,* 125 USPQ 416.

Also it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the selected iron amount in order to produce the claimed ranges (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula (column 10, line 37) and/or based on the other ingredients present in the formula which may react with the type of iron chosen) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*).

Referring to claim 25, it is not known if the amount of iron present in Barrett-Reis formula is from about 20 mg to 50 mg per 100 g of human milk fortifier solids (other components of Barrett-Reis's powder) however it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the iron amount (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula(column 10, line 37)) in order to produce known effects for the intended

application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980)*. For example, if the formula is administered to a low weight preterm infant during the 1st 2 months of life and the infant has not had a large amount of blood loss, one of ordinary skill would have realized that since the infant would have sufficient iron stores per body mass, the infant would not have required as much iron as a larger infant and one of ordinary skill would have thus been motivated to provide the preterm infant with iron values within the lower bounds of the claimed range to meet the infant's needs (column 10, lines 35-45) (a larger infant require larger iron content values than the smaller, low weight infant so one of ordinary skill would have been motivated to provide more iron in the formula for a larger infant to meet the larger infant's needs. Also, if the infant is anemic, it would have been obvious to one of ordinary skill to provide iron closer to the upper bound of the claimed range in order to treat the degree of the anemia). Furthermore, it would have been obvious to one of ordinary skill to thus increase or decrease the iron content depending on the needs and/or conditions of the infant in order to provide a human milk fortifier that fits the needs of the specific infant.

Referring to claim 24, it is not known if the amount of iron present in Barrett-Reis formula is from about 5 mg to 25 mg per 100 g of human milk fortifier solids (other components of Barrett-Reis's powder) however it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the iron amount (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula(column 10, line 37)) in order to produce known effects for the intended

application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980)*. For example, if the formula is administered to a low weight preterm infant during the 1st 2 months of life and the infant has not had a large amount of blood loss, one of ordinary skill would have realized that since the infant would have sufficient iron stores per body mass, the infant would not have required as much iron as a larger infant and one of ordinary skill would have thus been motivated to provide the preterm infant with iron values within the lower bounds of the claimed range to meet the infant's needs (column 10, lines 35-45) (a larger infant require larger iron content values than the smaller, low weight infant so one of ordinary skill would have been motivated to provide more iron in the formula for a larger infant to meet the larger infant's needs. Also, if the infant is anemic, it would have been obvious to one of ordinary skill to provide iron closer to the upper bound of the claimed range in order to treat the degree of the anemia). Furthermore, it would have been obvious to one of ordinary skill to thus increase or decrease the iron content depending on the needs and/or conditions of the infant in order to provide a human milk fortifier that fits the needs of the specific infant.

Referring to claim 26, Iron anemia NPL teaches ferrous fumarte (see iron anemia NPL, second paragraph, page 3).

Referring to claim 27, Barrett-Reis teaches 24-55% protein, 1-30% fats (or lipids), and 15 to 75% carbohydrates of the powder (or fortifier solids, see abstract). Per

100 grams of fortifier solids (powder), the amounts would be from 24-55 g protein, 1-30 g fats (or lipids), and 15 to 75 g.

Referring to claim 28, Barrett-Reis teaches 24-55% protein, 1-30% fats (or lipids), and 15 to 75% carbohydrates of the powder (or fortifier solids, see abstract). Per 100 grams of fortifier solids (powder), the amounts would be from 24-55 g protein, 1-30 g fats (or lipids), and 15 to 75 g. The ranges taught by Barret-Reis substantially overlap and thus are considered to anticipate the claimed ranges.

Additionally, one of ordinary skill in the art at the time of the invention would have considered the invention to have been obvious because the compositional proportions taught by Barret-Reis overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

"The normal desire of scientist or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.", *In re Petersen* 65 USPQ2d 1379 (CAFC 2003).

Referring to claim 29, the composition of Barrett-Reis can be a powder (see abstract).

Referring to claim 30, Barrett-Reis discloses that liquid forms of preterm fortifiers are known (column 2, line 5). Barrett-Reis further discloses that liquid forms of milk fortifiers are advantageous when the mothers milk supply is limited (column 2, lines 61-62). Barrett-Reis does not explicitly disclose a liquid form of the composition however Barrett-Reis does disclose the use of liquid ingredients in the creation of the formula(column 13, line 5). It would have been obvious to one of ordinary skill in the art at the time of the invention to produce a liquid form of the formula of Barrett-Reis by using mostly liquid forms of the compositional ingredients (column 13, line 5) in order to accommodate mothers who can not maintain the level of milk productions levels that is required of their infants.

Referring to claim 31, Barrett-Reis does not teach or disclose the claimed percentages however it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the amounts of the solids compared to the amount of the water in order to produce a known fluidity (viscosity) of the composition for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*. 617, F.2d 272,205 USPQ 215 (CCPA 1980). Furthermore, depending on how thick or thin (viscous or less viscous) one of ordinary skill wanted the formula, it would have been obvious to one of ordinary skill to adjust the ratio of the solids to the liquids in order to

produce this desired viscosity based on what is desired by the infants consuming this formula.

Referring to claim 32, Barrett-Reis does not teach or disclose the claimed percentages however it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the amounts of the solids compared to the amount of the water in order to produce a known fluidity (viscosity) of the composition for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*. 617, F.2d 272,205 USPQ 215 (CCPA 1980). Furthermore, depending on how thick or thin (viscous or less viscous) one of ordinary skill wanted the formula, it would have been obvious to one of ordinary skill to adjust the ratio of the solids to the liquids in order to produce this desired viscosity based on what is desired by the infants consuming this formula.

Referring to claim 33, Barrett-Reis does not teach or disclose the claimed ratios however the composition of Barrett-Reis in view of disclosure could be used in human milk in the claimed ratios.

Referring to claim 63, Barrett-Reis teaches a powdered human milk fortifier comprising protein, carbohydrates, and fats (or lipids) (see abstract). It is not known if the amount of iron present in Barrett-Reis formula is from about 15 mg to 110 mg per

100 g of human milk fortifier solids (other components of Barrett-Reis's powder) however it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the iron amount (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula(column 10, line 37)) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*). For example, if the formula is administered to a low weight preterm infant during the 1st 2 months of life and the infant has not had a large amount of blood loss, one of ordinary skill would have realized that since the infant would have sufficient iron stores per body mass, the infant would not have required as much iron as a larger infant and one of ordinary skill would have thus been motivated to provide the preterm infant with iron values within the lower bounds of the claimed range to meet the infant's needs (column 10, lines 35-45) (a larger infant require larger iron content values than the smaller, low weight infant so one of ordinary skill would have been motivated to provide more iron in the formula for a larger infant to meet the larger infant's needs. Also, if the infant is anemic, it would have been obvious to one of ordinary skill to provide iron closer to the upper bound of the claimed range in order to treat the degree of the anemia). Furthermore, it would have been obvious to one of ordinary skill to thus increase or decrease the iron content depending on the needs and/or conditions of the infant in order to provide a human milk fortifier that fits the needs of the specific infant.

Referring to **claim 63** again, it is also not known if the type of iron taught by Bridget-Reis is soluble unbound, insoluble, or a combination of the two. Iron anemia NPL teaches that iron preparations that are soluble in water or dilute acids are generally of high bioavailability and forms of iron that are insoluble in water or dilute acids solutions are of low bioavailability (see iron anemia NPL iron anemia top of page 2). Water-soluble iron tends to react with various components of food to produce oxidative rancidity (iron anemia NPL second paragraph of page 3). It is also known that the greater the solubility (and, the greater the bioavailability) of a metallic iron powder, the greater its chemical reactivity and the less suitable it is for food fortification (iron anemia NPL second paragraph of page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to select soluble iron or insoluble iron taught by iron anemia NPL for use with the invention of Bridget-Reis since it has been held to be within the general skill of the worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin,* 125 USPQ 416.

Also it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the selected iron amount in order to produce the claimed ranges (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula (column 10, line 37) and/or based on the other ingredients present in the formula which may react with the type of iron chosen) in order to produce known effects for the intended application, since it has been held that discovering an

optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*).

Referring to claim 64, it is also not known if the type of iron taught by Bridget-Reis is soluble unbound, insoluble, or a combination of the two. Iron anemia NPL teaches that iron preparations that are soluble in water or dilute acids are generally of high bioavailability and forms of iron that are insoluble in water or dilute acids solutions are of low bioavailability (see iron anemia NPL top of page 2). Water-soluble iron tends to react with various components of food to produce oxidative rancidity (iron anemia NPL second paragraph of page 3). It is also known that the greater the solubility (and, the greater the bioavailability) of a metallic iron powder, the greater its chemical reactivity and the less suitable it is for food fortification (iron anemia NPL second paragraph of page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to select soluble iron or insoluble iron for use with the invention of Bridget-Reis since it has been held to be within the general skill of the worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin,* 125 USPQ 416.

Also it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the selected iron amount in order to produce the claimed ranges (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula (column 10, line 37) and/or based on the other ingredients present in the formula which may react with the type of iron chosen) in order to produce

known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980)*.

Referring to claim 65, it is not known if the amount of iron present in Barrett-Reis formula is from about 20 mg to 50 mg per 100 g of human milk fortifier solids (other components of Barrett-Reis's powder) however it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the iron amount (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula(column 10, line 37)) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980)*. For example, if the formula is administered to a low weight preterm infant during the 1st 2 months of life and the infant has not had a large amount of blood loss, one of ordinary skill would have realized that since the infant would have sufficient iron stores per body mass, the infant would not have required as much iron as a larger infant and one of ordinary skill would have thus been motivated to provide the preterm infant with iron values within the lower bounds of the claimed range to meet the infant's needs (column 10, lines 35-45) (a larger infant require larger iron content values than the smaller, low weight infant so one of ordinary skill would have been motivated to provide more iron in the formula for a larger infant to meet the larger infant's needs. Also, if the infant is anemic, it would have been obvious to one of ordinary skill to

provide iron closer to the upper bound of the claimed range in order to treat the degree of the anemia). Furthermore, it would have been obvious to one of ordinary skill to thus increase or decrease the iron content depending on the needs and/or conditions of the infant in order to provide a human milk fortifier that fits the needs of the specific infant.

Referring to claim 66, iron anemia NPL teaches various forms of iron (see iron anemia NPL, second paragraph, page 3) all usable with the invention of Barret-Reis. Although ferrous sulfate and ferric sulfate can be used to fortify the food also, since ferrous sulfate is known to produce unfavorable side affects such as constipation (see Iron, Ferrous Sulfate-which forms of supplemental iron are best), it is somewhat favorable to not this compounds to the formula. Ferric sulfate absorbs poorly constipation (see Iron, Ferrous Sulfate-which forms of supplemental iron are best) so it's more favorable to use another iron that absorbs better. Because of these known negative attributes of ferrous sulfate and ferric sulfate, it would have been obvious to one having ordinary skill in the art at the time of the invention to thus fortify the formula without the addition of ferrous sulfate and ferric sulfate.

Referring to claim 67, iron anemia NPL teaches ferrous fumarte (see iron anemia NPL, second paragraph, page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to use ferrous fumarte with the invention of Barrett-Reis because ferrous fumarate is known to be gentle on the digestive system unlike other irons typically used to fortify foods (it does not interfere

with the proteolytic or distatic activies of the digestive system) (see Iron formulations in Pediatric Practice NPL, 1st paragraph of ferrous salts section). This feature would make it highly desirable for use in an infant formula.

Referring to claim 68, iron anemia NPL teaches ferrous fumarte (see iron anemia NPL, second paragraph, page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to use ferrous fumarte with the invention of Barrett-Reis because ferrous fumarate is known to be gentle on the digestive system unlike other irons typically used to fortify foods (it does not interfere with the proteolytic or distatic activies of the digestive system) (see Iron formulations in Pediatric Practice NPL, 1st paragraph of ferrous salts section). This feature would make it highly desirable for use in an infant formula.

Referring to claim 69, Barrett-Reis teaches 24-55% protein, 1-30% fats (or lipids), and 15 to 75% carbohydrates of the powder (or fortifier solids, see abstract). Per 100 grams of fortifier solids (powder), the amounts would be from 24-55 g protein, 1-30 g fats (or lipids), and 15 to 75 g.

Referring to claim 70, Barrett-Reis teaches 24-55% protein, 1-30% fats (or lipids), and 15 to 75% carbohydrates of the powder (or fortifier solids, see abstract). Per 100 grams of fortifier solids (powder), the amounts would be from 24-55 g protein, 1-30

g fats (or lipids), and 15 to 75 g. The ranges taught by Barret-Reis substantially overlap and thus are considered to anticipate the claimed ranges.

Additionally, one of ordinary skill in the art at the time of the invention would have considered the invention to have been obvious because the compositional proportions taught by Barret-Reis overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

"The normal desire of scientist or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.", *In re Petersen* 65 USPQ2d 1379 (CAFC 2003).

Referring to claim 71, the composition of Barrett-Reis can be a powder (see abstract).

Referring to claim 72, Barrett-Reis discloses that liquid forms of preterm fortifiers are known (column 2, line 5). Barrett-Reis further discloses that liquid forms of milk fortifiers are advantageous when the mothers milk supply is limited (column 2, lines 61-62). Barrett-Reis does not explicitly disclose a liquid form of the composition however Barrett-Reis does disclose the use of liquid ingredients in the creation of the

formula(column 13, line 5). It would have been obvious to one of ordinary skill in the art at the time of the invention to produce a liquid form of the formula of Barrett-Reis by using mostly liquid forms of the compositional ingredients (column 13, line 5) in order to accommodate mothers who can not maintain the level of milk productions levels that is required of their infants.

Referring to claim 73, Barrett-Reis does not teach or disclose the claimed percentages however it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the amounts of the solids compared to the amount of the water in order to produce a known fluidity (viscosity) of the composition for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*. 617, F.2d 272,205 USPQ 215 (CCPA 1980). Furthermore, depending on how thick or thin (viscous or less viscous) one of ordinary skill wanted the formula, it would have been obvious to one of ordinary skill to adjust the ratio of the solids to the liquids in order to produce this desired viscosity based on what is desired by the infants consuming this formula.

Referring to claim 74, Barrett-Reis does not teach or disclose the claimed percentages however it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the amounts of the solids compared to the amount

of the water in order to produce a known fluidity (viscosity) of the composition for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*. 617, F.2d 272,205 USPQ 215 (CCPA 1980). Furthermore, depending on how thick or thin (viscous or less viscous) one of ordinary skill wanted the formula, it would have been obvious to one of ordinary skill to adjust the ratio of the solids to the liquids in order to produce this desired viscosity based on what is desired by the infants consuming this formula.

Referring to claim 75, Barrett-Reis does not teach or disclose the claimed ratios however the composition of Barrett-Reis in view of disclosure could be used in human milk in the claimed ratios.

Referring to claim 81, Barrett-Reis teaches a powdered human milk fortifier comprising protein, carbohydrates, and fats (or lipids) (see abstract). It is not known if the type of iron taught by Bridget-Reis is soluble unbound, insoluble, or a combination of the two. Iron anemia NPL teaches that iron preparations that are soluble in water or dilute acids are generally of high bioavailability and forms of iron that are insoluble in water or dilute acids solutions are of low bioavailability (see iron anemia NPL top of page 2). Water-soluble iron tends to react with various components of food to produce oxidative rancidity (iron anemia NPL second paragraph of page 3). It is also known that

the greater the solubility (and, the greater the bioavailability) of a metallic iron powder, the greater its chemical reactivity and the less suitable it is for food fortification (iron anemia NPL second paragraph of page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to select soluble iron or insoluble iron for use with the invention of Bridget-Reis since it has been held to be within the general skill of the worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin,* 125 USPQ 416.

Also it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the selected iron amount in order to produce the claimed ranges (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula (column 10, line 37) and/or based on the other ingredients present in the formula which may react with the type of iron chosen) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*).

Referring to claim 82, it is not known if the amount of iron present in Barrett-Reis formula is from about 10 mg to 100 mg per 100 g of human milk fortifier solids (other components of Barrett-Reis's powder) however it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the iron amount (depending on the amount hemoglobin synthesis required based on the condition of the

baby receiving the formula(column 10, line 37)) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*). For example, if the formula is administered to a low weight preterm infant during the 1st 2 months of life and the infant has not had a large amount of blood loss, one of ordinary skill would have realized that since the infant would have sufficient iron stores per body mass, the infant would not have required as much iron as a larger infant and one of ordinary skill would have thus been motivated to provide the preterm infant with iron values within the lower bounds of the claimed range to meet the infant's needs (column 10, lines 35-45) (a larger infant require larger iron content values than the smaller, low weight infant so one of ordinary skill would have been motivated to provide more iron in the formula for a larger infant to meet the larger infant's needs. Also, if the infant is anemic, it would have been obvious to one of ordinary skill to provide iron closer to the upper bound of the claimed range in order to treat the degree of the anemia). Furthermore, it would have been obvious to one of ordinary skill to thus increase or decrease the iron content depending on the needs and/or conditions of the infant in order to provide a human milk fortifier that fits the needs of the specific infant.

Referring to **claim 82** again, it is also not known if the type of iron taught by Bridget-Reis is soluble unbound, insoluble, or a combination of the two. Iron anemia NPL teaches that iron preparations that are soluble in water or dilute acids are generally of high bioavailability and forms of iron that are insoluble in water or dilute acids

solutions are of low bioavailability (see iron anemia NPL iron anemia top of page 2). Water-soluble iron tends to react with various components of food to produce oxidative rancidity (iron anemia NPL second paragraph of page 3). It is also known that the greater the solubility (and, the greater the bioavailability) of a metallic iron powder, the greater its chemical reactivity and the less suitable it is for food fortification (iron anemia NPL second paragraph of page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to select soluble iron or insoluble iron taught by iron anemia NPL for use with the invention of Bridget-Reis since it has been held to be within the general skill of the worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin,* 125 USPQ 416.

Also it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the selected iron amount in order to produce the claimed ranges (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula (column 10, line 37) and/or based on the other ingredients present in the formula which may react with the type of iron chosen) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*).

Referring to claim 83, it is not known if the amount of iron present in Barrett-Reis formula is from about 20 mg to 50 mg per 100 g of human milk fortifier solids (other components of Barrett-Reis's powder) however it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the iron amount (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula(column 10, line 37)) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*). For example, if the formula is administered to a low weight preterm infant during the 1st 2 months of life and the infant has not had a large amount of blood loss, one of ordinary skill would have realized that since the infant would have sufficient iron stores per body mass, the infant would not have required as much iron as a larger infant and one of ordinary skill would have thus been motivated to provide the preterm infant with iron values within the lower bounds of the claimed range to meet the infant's needs (column 10, lines 35-45) (a larger infant require larger iron content values than the smaller, low weight infant so one of ordinary skill would have been motivated to provide more iron in the formula for a larger infant to meet the larger infant's needs. Also, if the infant is anemic, it would have been obvious to one of ordinary skill to provide iron closer to the upper bound of the claimed range in order to treat the degree of the anemia). Furthermore, it would have been obvious to one of ordinary skill to thus increase or decrease the iron content depending on the needs and/or conditions of the

Referring to claim 84, It is not known if the type of iron taught by Bridget-Reis is soluble unbound, insoluble, or a combination of the two. Iron anemia NPL teaches that iron preparations that are soluble in water or dilute acids are generally of high bioavailability and forms of iron that are insoluble in water or dilute acids solutions are of low bioavailability (see iron anemia NPL top of page 2). Water-soluble iron tends to react with various components of food to produce oxidative rancidity (iron anemia NPL second paragraph of page 3). It is also known that the greater the solubility (and, the greater the bioavailability) of a metallic iron powder, the greater its chemical reactivity and the less suitable it is for food fortification (iron anemia NPL second paragraph of page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to select soluble iron or insoluble iron for use with the invention of Bridget-Reis since it has been held to be within the general skill of the worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin,* 125 USPQ 416.

Also it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the selected iron amount in order to produce the claimed ranges (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula (column 10, line 37) and/or based on the other ingredients present in the formula which may react with the type of iron chosen) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*).

Referring to claim 85, iron anemia NPL teaches various forms of iron (see iron anemia NPL, second paragraph, page 3) all usable with the invention of Barret-Reis. Although ferrous sulfate and ferric sulfate can be used to fortify the food also, since ferrous sulfate is known to produce unfavorable side affects such as constipation (see Iron, Ferrous Sulfate-which forms of supplemental iron are best), it is somewhat favorable to not this compounds to the formula. Ferric sulfate absorbs poorly constipation (see Iron, Ferrous Sulfate-which forms of supplemental iron are best) so it's more favorable to use another iron that absorbs better. Because of these known negative attributes of ferrous sulfate and ferric sulfate, it would have been obvious to one having ordinary skill in the art at the time of the invention to thus fortify the formula without the addition of ferrous sulfate and ferric sulfate.

Referring to claim 86, Barrett-Reis teaches 24-55% protein, 1-30% fats (or lipids), and 15 to 75% carbohydrates of the powder (or fortifier solids, see abstract). Per 100 grams of fortifier solids (powder), the amounts would be from 24-55 g protein, 1-30 g fats (or lipids), and 15 to 75 g.

Referring to claim 87, Barrett-Reis teaches 24-55% protein, 1-30% fats (or lipids), and 15 to 75% carbohydrates of the powder (or fortifier solids, see abstract). Per 100 grams of fortifier solids (powder), the amounts would be from 24-55 g protein, 1-30

g fats (or lipids), and 15 to 75 g. The ranges taught by Barret-Reis substantially overlap and thus are considered to anticipate the claimed ranges.

Additionally, one of ordinary skill in the art at the time of the invention would have considered the invention to have been obvious because the compositional proportions taught by Barret-Reis overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

"The normal desire of scientist or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.", *In re Petersen* 65 USPQ2d 1379 (CAFC 2003).

Referring to claim 88, the composition of Barrett-Reis can be a powder (see abstract).

Referring to claim 89, Barrett-Reis discloses that liquid forms of preterm fortifiers are known (column 2, line 5). Barrett-Reis further discloses that liquid forms of milk fortifiers are advantageous when the mothers milk supply is limited (column 2, lines 61-62). Barrett-Reis does not explicitly disclose a liquid form of the composition however Barrett-Reis does disclose the use of liquid ingredients in the creation of the

formula(column 13, line 5). It would have been obvious to one of ordinary skill in the art at the time of the invention to produce a liquid form of the formula of Barrett-Reis by using mostly liquid forms of the compositional ingredients (column 13, line 5) in order to accommodate mothers who can not maintain the level of milk productions levels that is required of their infants.

Referring to claim 90, Barrett-Reis does not teach or disclose the claimed percentages however it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the amounts of the solids compared to the amount of the water in order to produce a known fluidity (viscosity) of the composition for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*. 617, F.2d 272,205 USPQ 215 (CCPA 1980). Furthermore, depending on how thick or thin (viscous or less viscous) one of ordinary skill wanted the formula, it would have been obvious to one of ordinary skill to adjust the ratio of the solids to the liquids in order to produce this desired viscosity based on what is desired by the infants consuming this formula.

Referring to claim 91, Barrett-Reis does not teach or disclose the claimed percentages however it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the amounts of the solids compared to the amount

of the water in order to produce a known fluidity (viscosity) of the composition for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*. 617, F.2d 272,205 USPQ 215 (CCPA 1980). Furthermore, depending on how thick or thin (viscous or less viscous) one of ordinary skill wanted the formula, it would have been obvious to one of ordinary skill to adjust the ratio of the solids to the liquids in order to produce this desired viscosity based on what is desired by the infants consuming this formula.

Referring to claim 92, Barrett-Reis does not teach or disclose the claimed ratios however the composition of Barrett-Reis in view of disclosure could be used in human milk in the claimed ratios.

Referring to claim 97, Barrett-Reis teaches a powdered human milk fortifier comprising protein, carbohydrates, and fats (or lipids) (see abstract). It is not known if the type of iron taught by Bridget-Reis is soluble unbound, insoluble, or a combination of the two. Iron anemia NPL teaches that iron preparations that are soluble in water or dilute acids are generally of high bioavailability and forms of iron that are insoluble in water or dilute acids solutions are of low bioavailability (see iron anemia NPL top of page 2). Water-soluble iron tends to react with various components of food to produce oxidative rancidity (iron anemia NPL second paragraph of page 3). It is also known that the greater the solubility (and, the greater the bioavailability) of a metallic iron powder,

the greater its chemical reactivity and the less suitable it is for food fortification (iron anemia NPL second paragraph of page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to select soluble iron or insoluble iron for use with the invention of Bridget-Reis since it has been held to be within the general skill of the worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin,* 125 USPQ 416.

Also it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the selected iron amount in order to produce the claimed ranges (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula (column 10, line 37) and/or based on the other ingredients present in the formula which may react with the type of iron chosen) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*).

Additionally, iron anemia NPL teaches various forms of iron (see iron anemia NPL, second paragraph, page 3) all usable with the invention of Barret-Reis. Although ferrous sulfate and ferric sulfate can be used to fortify the food also, since ferrous sulfate is known to produce unfavorable side affects such as constipation (see Iron, Ferrous Sulfate-which forms of supplemental iron are best), it is somewhat favorable to not this compounds to the formula. Ferric sulfate absorbs poorly constipation (see Iron, Ferrous Sulfate-which forms of supplemental iron are best) so it's more favorable to use

another iron that absorbs better. Because of these known negative attributes of ferrous sulfate and ferric sulfate, it would have been obvious to one having ordinary skill in the art at the time of the invention to thus fortify the formula without the addition of ferrous sulfate and ferric sulfate.

Referring to claim 98, the composite invention of the references mentioned in examiner's address of claim 97 contains no ferrous sulfate or ferric sulfate. 0 is less than 0.1 mg.

Referring to claim 99, it is also not known if the type of iron taught by Bridget-Reis is soluble unbound, insoluble, or a combination of the two. Iron anemia NPL teaches that iron preparations that are soluble in water or dilute acids are generally of high bioavailability and forms of iron that are insoluble in water or dilute acids solutions are of low bioavailability (see iron anemia NPL top of page 2). Water-soluble iron tends to react with various components of food to produce oxidative rancidity (iron anemia NPL second paragraph of page 3). It is also known that the greater the solubility (and, the greater the bioavailability) of a metallic iron powder, the greater its chemical reactivity and the less suitable it is for food fortification (iron anemia NPL second paragraph of page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to select soluble iron or insoluble iron for use with the invention of Bridget-Reis since it has been held to be within the general skill of the

worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin,* 125 USPQ 416.

Also it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the selected iron amount in order to produce the claimed ranges (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula (column 10, line 37) and/or based on the other ingredients present in the formula which may react with the type of iron chosen) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*).

Referring to claim 100, the abstract of Barrett–Reis teaches administering the composition, which has been added to human milk, to an infant.

Referring to claim 101, the abstract of Barrett–Reis teaches administering the composition, which has been added to human milk, to an infant.

Referring to claim 102, the abstract of Barrett–Reis teaches administering the composition, which has been added to human milk, to an infant.

Referring to claim 104, the abstract of Barrett–Reis teaches administering the composition, which has been added to human milk, to an infant.

Referring to claim 105, the abstract of Barrett–Reis teaches administering the composition, which has been added to human milk, to an infant.

Referring to claim 106, the abstract of Barrett–Reis teaches administering the composition, which has been added to human milk, to an infant.

Referring to claim 107, the abstract of Barrett–Reis teaches administering the composition to an infant.

Referring to claim 108, the abstract of Barrett–Reis teaches administering the composition, which has been added to human milk, to an infant.

Referring to claim 111, the abstract of Barrett–Reis teaches administering the composition, which has been added to human milk, to an infant.

Referring to claim 112, the abstract of Barrett–Reis teaches administering the composition, which has been added to human milk, to an infant.

Referring to claim 113, the abstract of Barrett–Reis teaches administering the composition, which has been added to human milk, to an infant.

Claims 16-20, 34-49, 76-80, 93-96, 102,109 rejected under 35 U.S.C. 103(a) as being unpatentable over Bridget Barrett-Reis, US-Patent 6,294,206 in view of iron anemia NPL and in view of Richard J. Schanler, "Suitability of Human Milk for the Low Birthweight Infant" and as evidenced by solubility NPL and Iron Formulations in Pediatic Practice NPL.

Referring to claim 16, the references teach the contents mentioned in examiner's address of claim 1 however the references fail to teach a iron availability agent. Schanler teaches calcium glycerophosphate (last paragraph of page 215) which is considered to be a iron availability agent (in 0047 of applicant's specification, calcium glycerophosphate is listed as a potential iron availability agent). It would have been obvious to one of ordinary skill in the art at the time of the invention to further add calcium glycerophosphate to the composition of Barrett-Reis in order to provide a source of calcium and phosphorous to the formula which would enhance infant growth (page 215, paragraph 2)

Referring to claim 17, depending on the amount of calcium glycerophosphate added to the formula in the composite invention of **claim 16**, the concentration of soluble unbound iron in the composition would decrease by a certain percent. It would have thus been obvious to one having ordinary skill in the art at the time of the invention to adjust the concentration of iron for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill

in the art. *In re Boesch,* 617 F.2d 272,205 USPQ 215 (CCPA). One of ordinary skill in the art would have thus understood the effects of adding varying amounts of calcium glycerophosphate to the formula in order to reduce the iron concentration by an amount that would be necessary for the specific infant that would be taking this formula.

Referring to claim 18, depending on the amount of calcium glycerophosphate added to the formula in the composite invention of **claim 16**, the concentration of soluble unbound iron in the composition would decrease by a certain percent. It would have thus been obvious to one having ordinary skill in the art at the time of the invention to adjust the concentration of iron for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272,205 USPQ 215 (CCPA). One of ordinary skill in the art would have thus understood the effects of adding varying amounts of calcium glycerophosphate to the formula in order to reduce the iron concentration by an amount that would be necessary for the specific infant that would be taking this formula.

Referring to claim 19, it is not known if the composite invention of **claim 16** would comprise calcium glycerophosphate in an amount of up to 10 g of phosphate ions per 100 g of fortifier solids however it would have thus been obvious to one having ordinary skill in the art at the time of the invention to adjust the amount of calcium glycerophosphate relative to the amount of fortifier solids for the intended application, since it has been held that discovering an optimum value of a result effective variable

involves only routine skill in the art. *In re Boesch,* 617 F.2d 272,205 USPQ 215 (CCPA). One of ordinary skill in the art would have thus understood the effects of adding varying amounts of calcium glycerophosphate to the formula in order to produce a formula with properties catered towards a specific type of infant.

Referring to claim 20, Schanler teaches calcium glycerophosphate (last paragraph of page 215).

Referring to claim 34, Barrett-Reis teaches a powdered human milk fortifier comprising protein, carbohydrates, and fats (or lipids) (see abstract). It is not known if the amount of iron present in Barrett-Reis formula is from about 15 mg to 110 mg per 100 g of human milk fortifier solids (other components of Barrett-Reis's powder) however it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the iron amount (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula(column 10, line 37)) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*). For example, if the formula is administered to a low weight preterm infant during the 1st 2 months of life and the infant has not had a large amount of blood loss, one of ordinary skill would have realized that since the infant would have sufficient iron stores per body mass, the infant would not have required as much iron as a larger infant and one of ordinary skill would

have thus been motivated to provide the preterm infant with iron values within the lower bounds of the claimed range to meet the infant's needs (column 10, lines 35-45) (a larger infant require larger iron content values than the smaller, low weight infant so one of ordinary skill would have been motivated to provide more iron in the formula for a larger infant to meet the larger infant's needs. Also, if the infant is anemic, it would have been obvious to one of ordinary skill to provide iron closer to the upper bound of the claimed range in order to treat the degree of the anemia). Furthermore, it would have been obvious to one of ordinary skill to thus increase or decrease the iron content depending on the needs and/or conditions of the infant in order to provide a human milk fortifier that fits the needs of the specific infant.

Additionally, the references fail to teach a iron availability agent. Schanler teaches calcium glycerophosphate (last paragraph of page 215) which is considered to be a iron availability agent (in 0047 of applicant's specification, calcium glycerophosphate is listed as a potential iron availability agent). It would have been obvious to one of ordinary skill in the art at the time of the invention to further add calcium glycerophosphate to the composition of Barrett-Reis in order to provide a source of calcium and phosphorous to the formula which would enhance infant growth (page 215, paragraph 2)

Referring to claim 35, it is not known if the amount of iron present in Barrett-Reis formula is from about 20 mg to 50 mg per 100 g of human milk fortifier solids (other components of Barrett-Reis's powder) however it would have been obvious to one of

ordinary skill in the art at the time of the invention to vary the iron amount (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula(column 10, line 37)) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*). For example, if the formula is administered to a low weight preterm infant during the 1st 2 months of life and the infant has not had a large amount of blood loss, one of ordinary skill would have realized that since the infant would have sufficient iron stores per body mass, the infant would not have required as much iron as a larger infant and one of ordinary skill would have thus been motivated to provide the preterm infant with iron values within the lower bounds of the claimed range to meet the infant's needs (column 10, lines 35-45) (a larger infant require larger iron content values than the smaller, low weight infant so one of ordinary skill would have been motivated to provide more iron in the formula for a larger infant to meet the larger infant's needs. Also, if the infant is anemic, it would have been obvious to one of ordinary skill to provide iron closer to the upper bound of the claimed range in order to treat the degree of the anemia). Furthermore, it would have been obvious to one of ordinary skill to thus increase or decrease the iron content depending on the needs and/or conditions of the infant in order to provide a human milk fortifier that fits the needs of the specific infant

Referring to claim 36, depending on the amount of calcium glycerophosphate added to the formula in the composite invention of **claim 34**, the concentration of

soluble unbound iron in the composition would decrease by a certain percent. It would have thus been obvious to one having ordinary skill in the art at the time of the invention to adjust the concentration of iron for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272,205 USPQ 215 (CCPA). One of ordinary skill in the art would have thus understood the effects of adding varying amounts of calcium glycerophosphate to the formula in order to reduce the iron concentration by an amount that would be necessary for the specific infant that would be taking this formula.

Referring to claim 37, depending on the amount of calcium glycerophosphate added to the formula in the composite invention of **claim 34**, the concentration of soluble unbound iron in the composition would decrease by a certain percent. It would have thus been obvious to one having ordinary skill in the art at the time of the invention to adjust the concentration of iron for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272,205 USPQ 215 (CCPA). One of ordinary skill in the art would have thus understood the effects of adding varying amounts of calcium glycerophosphate to the formula in order to reduce the iron concentration by an amount that would be necessary for the specific infant that would be taking this formula.

Referring to claim 38, it is not known if the composite invention of **claim 19** would comprise calcium glycerophosphate in an amount of up to 10 g of phosphate ions

per 100 g of fortifier solids however it would have thus been obvious to one having ordinary skill in the art at the time of the invention to adjust the amount of calcium glycerophosphate relative to the amount of fortifier solids for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272,205 USPQ 215 (CCPA). One of ordinary skill in the art would have thus understood the effects of adding varying amounts of calcium glycerophosphate to the formula in order to produce a formula with properties catered towards a specific type of infant.

Referring to claim 39, Schanler teaches calcium glycerophosphate (last paragraph of page 215).

Referring to claim 40, it is also not known if the type of iron taught by Bridget-Reis is soluble unbound, insoluble, or a combination of the two. Iron anemia NPL teaches that iron preparations that are soluble in water or dilute acids are generally of high bioavailability and forms of iron that are insoluble in water or dilute acids solutions are of low bioavailability (see iron anemia NPL iron anemia top of page 2). Water-soluble iron tends to react with various components of food to produce oxidative rancidity (iron anemia NPL second paragraph of page 3). It is also known that the greater the solubility (and, the greater the bioavailability) of a metallic iron powder, the greater its chemical reactivity and the less suitable it is for food fortification (iron anemia NPL second paragraph of page 3). It would have been obvious to one having ordinary

skill in the art at the time of the invention to select soluble iron or insoluble iron taught by iron anemia NPL for use with the invention of Bridget-Reis since it has been held to be within the general skill of the worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin,* 125 USPQ 416.

Also it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the selected iron amount in order to produce the claimed ranges (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula (column 10, line 37) and/or based on the other ingredients present in the formula which may react with the type of iron chosen) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*).

Referring to claim 41, it is also not known if the type of iron taught by Bridget-Reis is soluble unbound, insoluble, or a combination of the two. Iron anemia NPL teaches that iron preparations that are soluble in water or dilute acids are generally of high bioavailability and forms of iron that are insoluble in water or dilute acids solutions are of low bioavailability (see iron anemia NPL top of page 2). Water-soluble iron tends to react with various components of food to produce oxidative rancidity (iron anemia NPL second paragraph of page 3). It is also known that the greater the solubility (and, the greater the bioavailability) of a metallic iron powder, the greater its chemical

reactivity and the less suitable it is for food fortification (iron anemia NPL second paragraph of page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to select soluble iron or insoluble iron for use with the invention of Bridget-Reis since it has been held to be within the general skill of the worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin,* 125 USPQ 416.

Also it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the selected iron amount in order to produce the claimed ranges (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula (column 10, line 37) and/or based on the other ingredients present in the formula which may react with the type of iron chosen) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*).

Referring to claim 42, iron anemia NPL teaches various forms of iron (see iron anemia NPL, second paragraph, page 3) all usable with the invention of Barret-Reis. Although ferrous sulfate and ferric sulfate can be used to fortify the food also, since ferrous sulfate is known to produce unfavorable side affects such as constipation (see Iron, Ferrous Sulfate-which forms of supplemental iron are best), it is somewhat favorable to not this compounds to the formula. Ferric sulfate absorbs poorly constipation (see Iron, Ferrous Sulfate-which forms of supplemental iron are best) so it's

more favorable to use another iron that absorbs better. Because of these known negative attributes of ferrous sulfate and ferric sulfate, it would have been obvious to one having ordinary skill in the art at the time of the invention to thus fortify the formula without the addition of ferrous sulfate and ferric sulfate.

Referring to claim 43, Barrett-Reis teaches 24-55% protein, 1-30% fats (or lipids), and 15 to 75% carbohydrates of the powder (or fortifier solids, see abstract). Per 100 grams of fortifier solids (powder), the amounts would be from 24-55 g protein, 1-30 g fats (or lipids), and 15 to 75 g.

Referring to claim 44, Barrett-Reis teaches 24-55% protein, 1-30% fats (or lipids), and 15 to 75% carbohydrates of the powder (or fortifier solids, see abstract). Per 100 grams of fortifier solids (powder), the amounts would be from 24-55 g protein, 1-30 g fats (or lipids), and 15 to 75 g. The ranges taught by Barret-Reis substantially overlap and thus are considered to anticipate the claimed ranges.

Additionally, one of ordinary skill in the art at the time of the invention would have considered the invention to have been obvious because the compositional proportions taught by Barret-Reis overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

"The normal desire of scientist or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.", *In re Petersen* 65 USPQ2d 1379 (CAFC 2003).

Referring to claim 45, the composition of Barrett-Reis can be a powder (see abstract).

Referring to claim 46, Barrett-Reis discloses that liquid forms of preterm fortifiers are known (column 2, line 5). Barrett-Reis further discloses that liquid forms of milk fortifiers are advantageous when the mothers milk supply is limited (column 2, lines 61-62). Barrett-Reis does not explicitly disclose a liquid form of the composition however Barrett-Reis does disclose the use of liquid ingredients in the creation of the formula(column 13, line 5). It would have been obvious to one of ordinary skill in the art at the time of the invention to produce a liquid form of the formula of Barrett-Reis by using mostly liquid forms of the compositional ingredients (column 13, line 5) in order to accommodate mothers who can not maintain the level of milk productions levels that is required of their infants.

Referring to claim 47, Barrett-Reis does not teach or disclose the claimed percentages however it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the amounts of the solids compared to the amount

of the water in order to produce a known fluidity (viscosity) of the composition for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*. 617, F.2d 272,205 USPQ 215 (CCPA 1980). Furthermore, depending on how thick or thin (viscous or less viscous) one of ordinary skill wanted the formula, it would have been obvious to one of ordinary skill to adjust the ratio of the solids to the liquids in order to produce this desired viscosity based on what is desired by the infants consuming this formula.

Referring to claim 48, Barrett-Reis does not teach or disclose the claimed percentages however it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the amounts of the solids compared to the amount of the water in order to produce a known fluidity (viscosity) of the composition for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*. 617, F.2d 272,205 USPQ 215 (CCPA 1980). Furthermore, depending on how thick or thin (viscous or less viscous) one of ordinary skill wanted the formula, it would have been obvious to one of ordinary skill to adjust the ratio of the solids to the liquids in order to produce this desired viscosity based on what is desired by the infants consuming this formula.

Referring to claim 49, Barrett-Reis does not teach or disclose the claimed ratios however the composition of Barrett-Reis in view of disclosure could be used in human milk in the claimed ratios.

Referring to claim 76, the references teach the contents mentioned in examiner's address of claim 63 however the references fail to teach a iron availability agent. Schanler teaches calcium glycerophosphate (last paragraph of page 215) which is considered to be a iron availability agent (in 0047 of applicant's specification, calcium glycerophosphate is listed as a potential iron availability agent). It would have been obvious to one of ordinary skill in the art at the time of the invention to further add calcium glycerophosphate to the composition of Barrett-Reis in order to provide a source of calcium and phosphorous to the formula which would enhance infant growth (page 215, paragraph 2)

Referring to claim 77, depending on the amount of calcium glycerophosphate added to the formula in the composite invention of **claim 76**, the concentration of soluble unbound iron in the composition would decrease by a certain percent. It would have thus been obvious to one having ordinary skill in the art at the time of the invention to adjust the concentration of iron for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272,205 USPQ 215 (CCPA). One of ordinary skill in the art would have thus understood the effects of adding varying amounts of calcium

glycerophosphate to the formula in order to reduce the iron concentration by an amount that would be necessary for the specific infant that would be taking this formula.

Referring to claim 78, depending on the amount of calcium glycerophosphate added to the formula in the composite invention of **claim 76**, the concentration of soluble unbound iron in the composition would decrease by a certain percent. It would have thus been obvious to one having ordinary skill in the art at the time of the invention to adjust the concentration of iron for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272,205 USPQ 215 (CCPA). One of ordinary skill in the art would have thus understood the effects of adding varying amounts of calcium glycerophosphate to the formula in order to reduce the iron concentration by an amount that would be necessary for the specific infant that would be taking this formula.

Referring to claim 79, it is not known if the composite invention of **claim 76** would comprise calcium glycerophosphate in an amount of up to 10 g of phosphate ions per 100 g of fortifier solids however it would have thus been obvious to one having ordinary skill in the art at the time of the invention to adjust the amount of calcium glycerophosphate relative to the amount of fortifier solids for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272,205 USPQ 215 (CCPA). One of ordinary skill in the art would have thus understood the effects of adding varying

amounts of calcium glycerophosphate to the formula in order to produce a formula with properties catered towards a specific type of infant.

Referring to claim 80, Schanler teaches calcium glycerophosphate (last paragraph of page 215).

Referring to claim 93, the references teach the contents mentioned in examiner's address of claim 81 however the references fail to teach a iron availability agent. Schanler teaches calcium glycerophosphate (last paragraph of page 215) which is considered to be a iron availability agent (in 0047 of applicant's specification, calcium glycerophosphate is listed as a potential iron availability agent). It would have been obvious to one of ordinary skill in the art at the time of the invention to further add calcium glycerophosphate to the composition of Barrett-Reis in order to provide a source of calcium and phosphorous to the formula which would enhance infant growth (page 215, paragraph 2)

Referring to claim 94, depending on the amount of calcium glycerophosphate added to the formula in the composite invention of **claim 93**, the concentration of soluble unbound iron in the composition would decrease by a certain percent. It would have thus been obvious to one having ordinary skill in the art at the time of the invention to adjust the concentration of iron for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill

in the art. *In re Boesch,* 617 F.2d 272,205 USPQ 215 (CCPA). One of ordinary skill in the art would have thus understood the effects of adding varying amounts of calcium glycerophosphate to the formula in order to reduce the iron concentration by an amount that would be necessary for the specific infant that would be taking this formula.

Referring to claim 95, it is not known if the composite invention of **claim 93** would comprise calcium glycerophosphate in an amount of up to 10 g of phosphate ions per 100 g of fortifier solids however it would have thus been obvious to one having ordinary skill in the art at the time of the invention to adjust the amount of calcium glycerophosphate relative to the amount of fortifier solids for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272,205 USPQ 215 (CCPA). One of ordinary skill in the art would have thus understood the effects of adding varying amounts of calcium glycerophosphate to the formula in order to produce a formula with properties catered towards a specific type of infant.

Referring to claim 96, Schanler teaches calcium glycerophosphate (last paragraph of page 215).

Referring to claim 102, the abstract of Barrett–Reis teaches administering the composition, which has been added to human milk, to an infant.

Referring to claim 109, the abstract of Barrett–Reis teaches administering the composition, which has been added to human milk, to an infant.

Claims 21, 51-62,103,110 rejected under 35 U.S.C. 103(a) as being unpatentable over Bridget Barrett-Reis, US-Patent 6,294,206 in view of iron anemia NPL and in view of Buford L. Nichols, US-Patent 4,977,137 and as evidenced by solubility NPL and Iron Formulations in Pediatic Practice NPL.

Referring to claim 21, the references teach the contents mentioned in examiner's address of claim 1 however the references fail to teach the addition of lactoferrin. Nichols teaches the addition of lactoferrin in infant formulas (abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to further enhance the formula of Barrett-Reis by adding lactoferrin (a known additive) because lactoferrin promotes the growth of the gastrointestinal tract of infants (abstract) and further reduces the risk of infections such as diarrhea (abstract).

Additionally, referring to the claimed ratio of 0.1 g of lactoferrin per mg of iron, one of ordinary skill in the art at the time of the invention would have realized that ratios around this range are necessary in order for the lactoferrin to have optimum health boosting effects.

Referring to claim 51, Barrett-Reis teaches a powdered human milk fortifier comprising protein, carbohydrates, and fats (or lipids) (see abstract). Additionally,

Barrett-Reis teaches that the composition can further comprise iron (column 11, line 44). Barrett-Reis fails to teach the addition of lactoferrin. Nichols teaches the addition of lactoferrin in infant formulas (abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to further enhance the formula of Barrett-Reis by adding lactoferrin (a known additive) because lactoferrin promotes the growth of the gastrointestinal tract of infants (abstract) and further reduces the risk of infections such as diarrhea (abstract).

Additionally, referring to the claimed ratio of 0.1 g of lactoferrin per mg of iron, one of ordinary skill in the art at the time of the invention would have realized that ratios around this range are necessary in order for the lactoferrin to have optimum health boosting effects.

Referring to claim 52, the references do not teach the larger claimed range of from about 0.7 g to about 3 g per mg of iron however one of ordinary skill in the art at the time of the invention would have recognized that it would have been advantageous to use lactoferrin content in this range for infants that may have gastrointestinal problems.

Referring to claim 53, it is not known if the amount of iron present in Barrett-Reis formula is from about 10 mg to 110 mg per 100 g of human milk fortifier solids (other components of Barrett-Reis's powder) however it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the iron amount

(depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula(column 10, line 37)) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*). For example, if the formula is administered to a low weight preterm infant during the 1st 2 months of life and the infant has not had a large amount of blood loss, one of ordinary skill would have realized that since the infant would have sufficient iron stores per body mass, the infant would not have required as much iron as a larger infant and one of ordinary skill would have thus been motivated to provide the preterm infant with iron values within the lower bounds of the claimed range to meet the infant's needs (column 10, lines 35-45) (a larger infant require larger iron content values than the smaller, low weight infant so one of ordinary skill would have been motivated to provide more iron in the formula for a larger infant to meet the larger infant's needs. Also, if the infant is anemic, it would have been obvious to one of ordinary skill to provide iron closer to the upper bound of the claimed range in order to treat the degree of the anemia). Furthermore, it would have been obvious to one of ordinary skill to thus increase or decrease the iron content depending on the needs and/or conditions of the infant in order to provide a human milk fortifier that fits the needs of the specific infant.

Referring to **claim 53** again, it is also not known if the type of iron taught by Bridget-Reis is soluble unbound, insoluble, or a combination of the two. Iron anemia NPL teaches that iron preparations that are soluble in water or dilute acids are generally

of high bioavailability and forms of iron that are insoluble in water or dilute acids solutions are of low bioavailability (see iron anemia NPL iron anemia top of page 2). Water-soluble iron tends to react with various components of food to produce oxidative rancidity (iron anemia NPL second paragraph of page 3). It is also known that the greater the solubility (and, the greater the bioavailability) of a metallic iron powder, the greater its chemical reactivity and the less suitable it is for food fortification (iron anemia NPL second paragraph of page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to select soluble iron or insoluble iron taught by iron anemia NPL for use with the invention of Bridget-Reis since it has been held to be within the general skill of the worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin,* 125 USPQ 416.

Also it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the selected iron amount in order to produce the claimed ranges (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula (column 10, line 37) and/or based on the other ingredients present in the formula which may react with the type of iron chosen) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*).

Referring to claim 54, it is also not known if the type of iron taught by Bridget-Reis is soluble unbound, insoluble, or a combination of the two. Iron anemia NPL teaches that iron preparations that are soluble in water or dilute acids are generally of high bioavailability and forms of iron that are insoluble in water or dilute acids solutions are of low bioavailability (see iron anemia NPL top of page 2). Water-soluble iron tends to react with various components of food to produce oxidative rancidity (iron anemia NPL second paragraph of page 3). It is also known that the greater the solubility (and, the greater the bioavailability) of a metallic iron powder, the greater its chemical reactivity and the less suitable it is for food fortification (iron anemia NPL second paragraph of page 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to select soluble iron or insoluble iron for use with the invention of Bridget-Reis since it has been held to be within the general skill of the worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin,* 125 USPQ 416.

Also it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the selected iron amount in order to produce the claimed ranges (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula (column 10, line 37) and/or based on the other ingredients present in the formula which may react with the type of iron chosen) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*).

Referring to claim 55, it is not known if the amount of iron present in Barrett-Reis formula is from about 20 mg to 50 mg per 100 g of human milk fortifier solids (other components of Barrett-Reis's powder) however it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the iron amount (depending on the amount hemoglobin synthesis required based on the condition of the baby receiving the formula(column 10, line 37)) in order to produce known effects for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980*). For example, if the formula is administered to a low weight preterm infant during the 1st 2 months of life and the infant has not had a large amount of blood loss, one of ordinary skill would have realized that since the infant would have sufficient iron stores per body mass, the infant would not have required as much iron as a larger infant and one of ordinary skill would have thus been motivated to provide the preterm infant with iron values within the lower bounds of the claimed range to meet the infant's needs (column 10, lines 35-45) (a larger infant require larger iron content values than the smaller, low weight infant so one of ordinary skill would have been motivated to provide more iron in the formula for a larger infant to meet the larger infant's needs. Also, if the infant is anemic, it would have been obvious to one of ordinary skill to provide iron closer to the upper bound of the claimed range in order to treat the degree of the anemia). Furthermore, it would have been obvious to one of ordinary skill to thus

increase or decrease the iron content depending on the needs and/or conditions of the infant in order to provide a human milk fortifier that fits the needs of the specific infant.

Referring to claim 56, Barrett-Reis teaches 24-55% protein, 1-30% fats (or lipids), and 15 to 75% carbohydrates of the powder (or fortifier solids, see abstract). Per 100 grams of fortifier solids (powder), the amounts would be from 24-55 g protein, 1-30 g fats (or lipids), and 15 to 75 g.

Referring to claim 57, Barrett-Reis teaches 24-55% protein, 1-30% fats (or lipids), and 15 to 75% carbohydrates of the powder (or fortifier solids, see abstract). Per 100 grams of fortifier solids (powder), the amounts would be from 24-55 g protein, 1-30 g fats (or lipids), and 15 to 75 g. The ranges taught by Barret-Reis substantially overlap and thus are considered to anticipate the claimed ranges.

Additionally, one of ordinary skill in the art at the time of the invention would have considered the invention to have been obvious because the compositional proportions taught by Barret-Reis overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

"The normal desire of scientist or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of

percentage ranges is the optimum combination of percentages.", *In re Petersen* 65 USPQ2d 1379 (CAFC 2003).

Referring to claim 58, the composition of Barrett-Reis can be a powder (see abstract).

Referring to claim 59, Barrett-Reis discloses that liquid forms of preterm fortifiers are known (column 2, line 5). Barrett-Reis further discloses that liquid forms of milk fortifiers are advantageous when the mothers milk supply is limited (column 2, lines 61-62). Barrett-Reis does not explicitly disclose a liquid form of the composition however Barrett-Reis does disclose the use of liquid ingredients in the creation of the formula(column 13, line 5). It would have been obvious to one of ordinary skill in the art at the time of the invention to produce a liquid form of the formula of Barrett-Reis by using mostly liquid forms of the compositional ingredients (column 13, line 5) in order to accommodate mothers who can not maintain the level of milk productions levels that is required of their infants.

Referring to claim 60, Barrett-Reis does not teach or disclose the claimed percentages however it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the amounts of the solids compared to the amount of the water in order to produce a known fluidity (viscosity) of the composition for the intended application, since it has been held that discovering an optimum value of a

result effective variable involves only routine skill in the art. *In re Boesch*. 617, F.2d 272,205 USPQ 215 (CCPA 1980). Furthermore, depending on how thick or thin (viscous or less viscous) one of ordinary skill wanted the formula, it would have been obvious to one of ordinary skill to adjust the ratio of the solids to the liquids in order to produce this desired viscosity based on what is desired by the infants consuming this formula.

Referring to claim 61, Barrett-Reis does not teach or disclose the claimed percentages however it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the amounts of the solids compared to the amount of the water in order to produce a known fluidity (viscosity) of the composition for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*. 617, F.2d 272,205 USPQ 215 (CCPA 1980). Furthermore, depending on how thick or thin (viscous or less viscous) one of ordinary skill wanted the formula, it would have been obvious to one of ordinary skill to adjust the ratio of the solids to the liquids in order to produce this desired viscosity based on what is desired by the infants consuming this formula.

Referring to claim 62, Barrett-Reis does not teach or disclose the claimed ratios however the composition of Barrett-Reis in view of disclosure could be used in human milk in the claimed ratios.

Referring to claim 103, the abstract of Barrett–Reis teaches administering the composition, which has been added to human milk, to an infant.

Referring to claim 110, the abstract of Barrett–Reis teaches administering the composition, which has been added to human milk, to an infant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PRESTON SMITH whose telephone number is (571)270-7084. The examiner can normally be reached on Mon-Fr 5:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on 571-272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Drew E Becker/
Primary Examiner, Art Unit 1794

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